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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,162	12/11/2001	Aaron Gershon Filler	GJE-18D1	6118

23557 7590 10/22/2002

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,162	FILLER ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/776,737
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicant's amendments and remarks submitted October 3, 2002 is acknowledged. Applicants' traverse of the restriction requirement is persuasive, and the restriction requirement mailed July 26, 2002 is herein withdrawn.

Claim Rejections 35 U.S.C. – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sierra et al. (US Patent No. 5,290,552, IDS U3) in view of Matsueda et al. (US Patent No. 4,927,916, IDS U1) and Bhargava et al.

Sierra et al. teach a composition comprising fibrinogen, factor XIII, thrombin, a therapeutic agent such as an antibiotic which may be in the form of particulate. See, column 4, lines 20-26 and lines 63-66 and column 5, lines 48-63. The composition further comprises an antifibrinolytic agent such as amino caproic acid (column 4, lines 50-60) and a growth factor (column 5, lines 7-10). Sierra et al further teach that the composition can serve as a drug delivery vehicle for controlled release. See, column 4, lines 63-66 and column 5, lines 48-63.

3. Sierra et al do not teach specifically that the therapeutic agent is a particulate radiotherapeutical agent.

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4. However, Matsueda et al. teach an antibody-based particulate radionuclide. See, particularly, column 7, lines 14-59, column 8, lines 7-66. Bhargava et al. teach antibody-based radionuclides and their employment as therapeutical agents. See the abstract.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the composition of Sierra et al as a delivery vehicle for the antibody-based radiotherapeutical agent of Bhargava et al. and Matsueda et al., i.e., employing the radiotherapeutical agent of Bhargava et al and Matsueda et al. as the therapeutical agent in the composition of Sierra et al.

A person of ordinary skill in the art would have been motivated to employ the composition of Sierra et al as a delivery vehicle for the antibody-based radiotherapeutical agent of Bhargava et al. and Matsueda et al. because that the composition of Sierra et al is known as a controlled release drug delivery vehicle. It would be reasonably expected to be similarly useful to deliver any known therapeutical agent. Further, employment of the method herein in a well-known therapy, such as brachytherapy or radiation synovectomy, is seen to be obvious since the method is obvious as discussed above.

Response to the Argument

Regarding the remarks that the particles are *immobilized in the glue*, note if a particle is not dissolved in the glue, it is considered to be immobilized in the glue.

Applicants' assertion that the claimed methods do not require the release of the immobilized particle is improper. The particles are eventually diffused, or absorbed. See the specification, particularly, pages 17-22. Further, it would be prima facie obvious to one of

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ordinary skill in the art, to employ tissue glue as carrier for the radiotherapeutical agent. Note holding the agent indefinite is a way of *controlled release*.

The application appears disclosing a composition wherein the radiotherapeutic particles are made by a particular method. See, page 5, lines 28 through page 9, line 37 and the example at pages 26-29. Claims drawn to subject matters, wherein the therapeutical particles are those as disclosed in the specification would be favorably considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Examiner



Shengjun Wang

October 18, 2002